

**REMARKS**

This Response is in reply to the Office Action mailed December 8, 2008. Claims 1-67 were pending in the application with each of the claims being rejected.

I. Claims 1, 3-4, 6-10, 12, 14-20, 23, 26-27, 29-31, 33-36, 62, and 64-67 were rejected under 35 U.S.C. 103(a) over U.S. Patent No. 6,048,342 (Zucherman '342) in view of U.S. Patent No. 4,834,757 (Brantigan '757) and in view of U.S. Patent Publication No. 2002/0016592 (Branch) and further in view of U.S. Patent No. 4,863,470 (Carter) or U.S. Patent No. 5,728,128 (Crickenberger).

Each of independent claims 1, 19, and 62 are directed to an implant with certain functional elements that are radiopaque and certain functional elements that are at least in part radiolucent. ***These elements perform a structural function during insertion of the implant or after insertion such as facilitating the insertion into the interspinous space and sizing and positioning the various elements of the implant. The elements are also constructed in a manner to facilitate visualization of the insertion and/or positioning relative to the spinous processes.*** The shaft is radiopaque and supports and positions the various elements of the implant and also allows for determining the position of the implant during x-ray imaging. The tissue expander is at least partly radiolucent and distracts the soft tissue and the spinous processes without impairing the view of the spinous processes during x-ray imaging.

*A. The combination of Zucherman '342, Brantigan '757, and Branch do not make the claim obvious*

Page 4 of the Office Action states the claimed invention is disclosed by Zucherman '342, Brantigan '757, and Brach. The Applicants disagree.

The Office Action admits that Zucherman '342 does not include an implant with a first portion that is radiolucent, or a second portion that is at least partially radiopaque (Office Action, page 3). The Office Action cites to Brantigan '757 for an implant that incorporates a radiolucent portion, and to Branch for an implant that is at least radiopaque. These references do not disclose these aspects.

Brantigan '757 discloses an implant that is entirely radiolucent (Col. 1, lines 32-35). It appears the reason for the entire implant to be radiolucent is to allow monitoring of bone growth with x-ray visualization (Col. 6, line 66 – Col. 7, line 5). There is no disclosure or suggestion within Brantigan '757 that only a discrete section of the implant be constructed of a radiolucent material and at least one second element be constructed at least in part of a radiopaque material. More particularly, there is no disclosure or suggestion that the tissue expander and spacer be constructed at least in part of a radiolucent material.

Branch discloses an interbody fusion graft and associated instrumentation, including an implant holder used for inserting the fusion graft into the patient. A gripping head of the implant holder may include a pin with a radiopaque portion to assist in viewing placement of the implant during surgery (§ 0009). ***However, the radiopaque portion is on the tool and not on the implant itself.*** Branch does not disclose that a discrete section of the implant can be constructed at least in part of a radiopaque material.

This combination does not disclose an implant with a shaft that is radiopaque, and a tissue expander and spacer that is at least in part radiolucent. Brantigan '757 discloses that the entire implant be constructed of a radiolucent material. Branch does not disclose an implant that is radiopaque, but rather a radiopaque tool for inserting an implant. Therefore, this combination does not make claim 1 obvious.

*B. Carter or Crickenberger do not remedy the failure to establish obviousness*

The Office Action on page 4 cites to Carter or Crickenberger as disclosing implants made of radiopaque and radiolucent materials. However, these references disclose elements of an implant that perform only one function and do not perform multiple functions such as the elements of claim 1. The radiopaque members of both Carter and Crickenberger are additional elements added to an implant or device specifically for the purpose of being visually observed during insertion into the patient and/or after insertion in the patient. These elements perform no other functions. The shaft and the tissue expander of claims 1, 19, and 62 are each constructed to perform multiple functions. A first function is a structural function such as facilitating insertion into the patient or providing a structure for spacing and/or sizing of the implant relative to the spinous processes. In addition, these elements perform a second function by being constructed of specific materials to assist in visualization of specific aspects of the implant during and/or after insertion.

Carter discloses an identification marker for a breast prosthesis. The breast prosthesis includes radiolucent gel placed within an exterior shell. A radiopaque identification marker is positioned on the breast prosthesis. The identification marker

provides for gathering information about the breast prosthesis after it is implanted within a patient through x-ray imaging and without resorting to surgery (Col. 2, lines 30-46). The identification marker functions only to assist in identifying the prosthesis after being implanted into the body. The identification marker does not perform any additional function such as facilitating insertion into the patient or supporting or positioning additional elements of the prosthesis. One of ordinary skill in the art would not know to make a component of an insert from a different type of material to allow the component to perform multiple functions. Carter discloses that an element constructed of a different material than the remainder of the implant performs one function.

Likewise, Crickenberger also discloses an element constructed of a different material for performing a single function. Crickenberger discloses a femoral neck anteversion guide that includes a radiolucent stem sized to fit into an intramedullary canal of a femur to provide a stable union between the stem and the femur (Col. 2, lines 43-51). The neck is preferably constructed entirely from radiolucent material (Col. 2, lines 64-67). One or more locator members are connected to the neck. The locator members are constructed of a radiopaque material to determine the position of the neck using x-ray imaging. (Col. 3, lines 13-18; Col. 5, lines 2-9). The locator members perform no additional functions such as facilitating insertion into the femur or supporting or positioning other elements of the guide. As with Carter, one of ordinary skill in the art would not know to make a functional component of an implant from a specific material such that the functional element can perform multiple functions.

For at least these reasons, independent claims 1, 19, and 62 and dependent claims 3-4, 6-10, 12, 14-18, 20, 23, 26-27, 29-31, 33-36, and 64-67 are not made obvious over this combination.

Claim 12 depends from claim 1 and further adds that the spacer is at least in part radiolucent. As explained above for claim 1, the cited combination does not make this aspect obvious and the Office Action fails to establish a prima facie case for obviousness in rejecting this claim.

Claim 14 depends from claim 1 and adds, *inter alia*, that the body, shaft, and first and second wings are radiopaque and the tissue expander and spacer are radiolucent such that under imaging the implant resembles an H-shape. The combination of Zucherman '342, Brantigan '757, Branch, and Carter or Crickenberger does not disclose these discrete sections including these properties. Further, the Office Action makes at best a conclusory statement that the subject matter of these claims is obvious, but does not appear to provide any explanation as to how this conclusion is reached. Conclusory statements are not adequate for establishing a prima facie case for obviousness. *In re Kahn*, 78 U.S.P.Q.2d at 1335.

Claim 67 depends from claim 62 and adds, *inter alia*, that the body, shaft, and wings are a radiopaque "H" on imaging films. The cited combination does not make this aspect obvious, and the Office Action fails to establish a prima facie case for obviousness in rejecting this claim.

II. Claims 2, 13, 21-22, 37, 39-41, 43-46, 47-50, 53-55, 57-61, and 63 were rejected under 35 U.S.C. 103(a) over Zucherman '342 in view of Brantigan '757 and in view of

Branch, and further in view of Carter or Crickenberger and further in view of U.S. Patent No. 5,192,327 (Brantigan '327).

Claims 2 and 13 depend from independent claim 1 and are not made obvious over this combination for at least the same reasons as independent claim 1.

Claims 21 and 22 depend from independent claim 19 and are not made obvious over this combination for at least the same reasons as independent claim 19.

Claim 63 depends from independent claim 62 and is not made obvious over this combination for at least the same reasons as independent claim 62.

Claims 37 and 47 require, *inter alia*, a radiopaque shaft and a tissue expander that is at least in part radiolucent. As stated above in Section I, these elements perform structural functions during insertion and/or after being implanted. Additionally, the properties provide for the shaft to be visible during x-ray imaging, while the expander is not visible. This allows a doctor to have a clearer view of the spine under x-ray imaging.

As stated above in Section I, Zucherman '342, Brantigan '757, Branch, and Carter or Crickenberger do not disclose an implant with functional elements that are also constructed from materials that facilitate observation during the insertion and/or positioning within a patient.

The Office Action includes Brantigan '327 to teach the use of a polyetherketone in implants (Office Action, page 5). Brantigan '327 discloses an implant with a uniform construction of the same material. Materials may include a carbon fiber reinforced polymer such as polyetheretherketone, a radiolucent plastic, and an inert metal (Col. 3, lines 9-13, Col. 4, lines 1-4). Brantigan '327 does not disclose that an implant may include separate sections that are constructed of materials with different properties.

Specifically, there does not appear to be any disclosure that the implant may include a tissue expander that is constructed at least in part from the radiolucent material, and the shaft constructed of a radiopaque material.

For at least these reasons, independent claims 37 and 47 and dependent claims 39-41, 43-46, 48-50, 53-55, and 57-61 are not made obvious over this combination.

III. Claims 5 and 28 were rejected under 35 USC 103(a) as being unpatentable over Zucherman '342, Brantigan '757, Branch, Carter or Crickenberger and U.S. Patent Publication 2001/0016592.

Claim 5 depends from independent claim 1 and is not made obvious for at least the same reasons as independent claim 1. Claim 28 depends from independent claim 19 and is not made obvious for at least the same reasons as independent claim 19.

IV. Claim 56 was rejected under 35 USC 103(a) as being unpatentable over Zucherman '342, Brantigan '757, Branch, Carter or Crickenberger and Brantigan '327, and U.S. Patent Publication 2001/0012938.

Claim 56 depends from independent claim 47 and is not made obvious for at least the same reasons as independent claim 47.

V. Claims 11, 24-25, and 32 were rejected under 35 USC 103(a) as being unpatentable over Zucherman '342, Brantigan '757, Branch, and Carter or Crickenberger.

Claim 11 depends from independent claim 1 and is not made obvious for at least the same reasons as independent claim 1.

Claims 24-25 and 32 depend from independent claim 19 and are not made obvious for at least the same reasons as independent claim 19.

VI. Claims 38 and 21-52 were rejected under 35 USC 103(a) as being unpatentable over Zucherman '342, Brantigan '757, Branch, and Carter or Crickenberger and Brantigan '327.

Claims 21-36 depend from independent claim 19 and are not made obvious for at least the same reasons as independent claim 19.

Independent claims 37 and 47 require, *inter alia*, a radiopaque shaft and a tissue expander that is at least in part radiolucent. As stated above in Section II, these elements perform structural functions during insertion and/or after being implanted. Additionally, the properties provide for the shaft to be visible during x-ray imaging, while the expander is not visible. This allows a doctor to have a clearer view of the spine under x-ray imaging.

As stated above in Sections I and II, Zucherman '342, Brantigan '757, Branch, and Carter or Crickenberger do not disclose functional elements that facilitate the insertion and/or positioning within a patient and are also constructed of materials to facilitate observation.

The Office Action includes Brantigan '327 to teach the use of a polyetherketone in implants (Office Action, page 5). Brantigan '327 discloses an implant with a uniform construction of the same material. Materials may include a carbon fiber reinforced



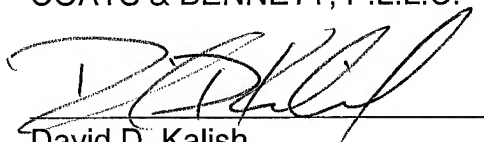
polymer such as polyetheretherketone, a radiolucent plastic, and an inert metal (Col. 3, lines 9-13, Col. 4, lines 1-4). Brantigan '327 does not disclose that an implant may include separate sections that are constructed of materials with different properties. Specifically, there does not appear to be any disclosure that the implant may include a tissue expander that is constructed from the radiolucent material, and the shaft constructed of a radiopaque material.

For at least these reasons, independent claims 37 and 47 and dependent claims 38-46 and 48-52 are not made obvious over this combination.

In view of the above amendments and remarks, the Applicants submit the present application is in condition for allowance, and such action is respectfully requested.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'D. Kalish', is written over a horizontal line.

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